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on NOVEMBER 24, 2004

Reg. No. 28,617

Attorney for Applicant(s)

J6721(C) 01-0505-CPI

PATENT

REPLY UNDER 37 CFR 1.116 EXPEDITED PROCEDURE TECHNOLOGY CENTER # 16/

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Customer Number:

000201

Attorney Docket No.: J6721(C)

Applicant:

Zhang et al. 10/056,968

Date of

Signature

Serial No.: Filed:

January 24, 2002

FOR:

THICKENER SYSTEM FOR COSMETIC COMPOSITIONS

UNUS No.:

01-0505-CPI

Group: 1617

Examiner: Shobha Kantamneni

Edgewater, New Jersey 07020

NOVEMBER 24, 2004

RESPONSE AFTER FINAL ACTION UNDER 37 C.F.R. § 1.116

MAIL STOP: AF

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

Sir:

The following comments are in response to the Office Action dated November 3, 2004. These comments are intended to advance the case to issue without delay.

Herewith presented is a Terminal Disclaimer to overcome the Provisional obviousness-type double patenting over claims 1-2, 5, 8-9 of co-pending US Application S/N 10/056,923. It is believed that the Terminal Disclaimer will render the obviousness-type double patenting rejection moot.

Although the Examiner has not re-specified the reasons for rejection, applicants proceed under the assumption that the claims are being rejected under 35 U.S.C. § 103(a) as unpatentable over Williams (US Patent 5,422,112) in view of Loffler et al. (InCosmetics, Dusseldorf) in view of Beerse et al. (US Patent 6,294,186). Applicants continue to traverse this rejection.

In the interest of economy, applicants provide response to the specific contentions expressed by the Examiner in the last Office Action. A broader more general set of arguments has been presented in previous amendments and the Examiner is requested to again review those presentations.

Earlier applicants submitted a Declaration Under Rule 132 demonstrating the unobvious nature of the present invention. Therein were compared a series of low pH lotions incorporating an alpha-hydroxy carboxylic acid. Sample 29A utilized xanthan gum as the sole thickener. Sample 29B utilized Aristoflex AVC® (ammonium acryloyldimethyltaurate/vinyl pyrrolidone) as the sole thickener. Sample 29C employed a combination of xanthan gum and Sepigel 305® (polyacrylamide). Sample 29D representing the present invention employed a thickener system of xanthan gum in combination with Aristoflex AVC®.

The four Samples were placed in a temperature controlled environment. They were subjected to a standard storage stability test that included storage at 37°C, 43°C, 50°C and cycle from 4°C to 43°C. Only Sample 29D representing the present invention remained stable without phase separation after 3 months under the storage conditions.

Based on the stability results, the applicants concluded that a combination of a polysaccharide (xanthan gum) with a taurate copolymer (Aristoflex AVC®) provided unexpected extended formula stability. This stability was better than polysaccharide or taurate copolymer alone. Compare Sample 29A and Sample 29B against Sample 29D.

In the last Office Action, the Examiner has dismissed these results. A first reason was that "the prior art US 5,422,112 thickening system Sample 29C a polysaccharide (xanthan gum) with a polyacrylamide (Sepigel 305®), survived 2 month storage stability which shows that it is only slightly inferior to Sample 29D. It has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233."

Applicants respectfully differ with the Examiner's technical and legal arguments. Technically survival for 3 months (Sample 29D) is 33% greater than survival for only 2 months (Sample 29C). The "inferior" performance is not just a slight difference. Secondly, Dr. Zhang submits a second Declaration Under Rule 132 in which she explains the critical nature of meeting 3 months storage stability under a temperature cycling regime. Any prototype formula that fails in 3 months is not further considered for commercialization. The 3 months period is not an arbitrary length but rather a well proven benchmark of stability success.

The cited case law is flawed relative to the present fact pattern. The rejection forming the basis of *In re Aller* concerned an invention wherein a single prior art reference was applied against the claims.

By contrast, the present rejection is over a combination of <u>three</u> references. Williams et al. does not disclose any taurate or copolymer. Loffler et al. does not disclose any polysaccharide gum. Beerse et al. does not disclose any alpha-hydroxy carboxylic acid. All three references are necessary to formulate the rejection. For this reason, the cited case law of *In re Aller* is not applicable.

Furthermore, *In re Aller* concerned a process. The "optimum and workable ranges" referred to process conditions of temperature and concentrations. By contrast, the present claims relate to ingredients of a composition. The cited case law is also for this reason not applicable.

Another argument of the Examiner was that "it is obvious to substitute Sepigel® a polyacrylamide polymer with another polyacrylamide based polymer Aristoflex AVC, in the thickening system for cosmetic compositions". It was argued that such substitution was appropriate "because of the expectation of achieving an oil-in-water emulsion that has good stability against degradation by high shear and UVA light and that provides good skin feel, low degree of stickiness."

Here the Examiner has misconstrued certain facts. Aristoflex AVC® does have an amide linkage but the monomer unit containing that linkage actually is a taurate. The taurate monomer features an anionic group which is a sulfonic ammonium salt. Unlike the anionic Aristoflex AVC® copolymer backbone, Sepigel® has a nonionic polyacrylamide backbone. The ionic strength and therefore viscosity building properties

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and compatibility of these thickeners would be expected to be quite different by those skilled in the art. Thus, the significant chemical and physical distinctions of these polymeric thickeners would not render them fungible one with another.

Applicants draw attention to the Williams et al. disclosure. Comparative experiments are outlined under Table II. Composition C combines xanthan gum with polyacrylamide (Sepigel®). The resultant emulsion was noted to provide a "clear separation lower half of lotion". Only when the further element of a magnesium aluminum silicate was added as in composition A, were those patentees able to achieve a stable emulsion. Anyone skilled in the art considering the Williams reference would therefore be directed away from using a polysaccharide such as xanthan gum in combination with a polyacrylamide.

In view of the foregoing comments, supplemental Declaration and Terminal Disclaimer, applicants request the Examiner to reconsider the rejection and now allow the claims.

Respectfully submitted,

Milton L. Honig

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NOVEMBER 24, 2004

MILTON L. HONIG Reg. No. 28,617

11/24/04 Date of Signature

Attorney for Applicant(s)

REPLY UNDER 37 CFR 1.116 EXPEDITED PROCEDURE TECHNOLOGY CENTER # 161

UNITED STATES DEPT. OF COMMERCE

Patent and Trademark Office

Alexandria, VA 22313-1450

P.O. Box 1450

COMMISSIONER FOR PATENTS

Customer Number:

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J6721(C) Zhang et al. 10/056,968

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January 24, 2002 THICKENER SYSTEM FOR COSMETIC COMPOSITIONS

UNUS No.:

For:

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Group: 1617 Examiner: Shobha Kantamneni

Edgewater, New Jersey 07020

November 24, 2004

MAIL STOP: AF

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

Sir:

Transmitted herewith is an AMENDMENT AFTER FINAL ACTION in the above-identified application.

No additional fee is required.

The fee has been calculated as shown below.

CLAIMS AS AMENDED

	(2) * Claims Remaining After Amendment		(4)** Highest No. Previously Paid For	(5) Present Extra	(6) Rate	(7) Additional Fee
Total Claims		Minus			\$ 18.00	
Independent Claims		Minus			\$ 84.00	
Multiple Claims					\$ 280.00	
TOTAL ADDITIONAL FEE FOR THIS AMENDMENT					\$	

^{*}If the entry in Column (2) is less than the entry in Column (4), write "0" in Column (5).

__ to Deposit Acct. #12-1155. Triplicate copies of this letter are enclosed.

The Commissioner is hereby authorized to charge any additional fees, which may be required to our deposit account No. 12-1155, including all required fees under

[X] 37 C.F.R. ∋ 1.16;

[X] 37 C.F.R. ∋ 1.17;

[X] 37 C.F.R. ≥ 1.18.

Triplicate copies of this letter are enclosed.

MLH/sm (201) 840-2403 Milton L. Honig Attorney of Record Reg. #28,617

^{**}If the "Highest No. Previously Paid For" is less than "20," write "20" in this space.